request for OMB approval. FDA estimates that submitting the information (online, telephone, email, or mail) will take 0.25 hours (*i.e.,* 15 minutes) per response.

FDA estimates the number of annual respondents to this collection of information will be 3,000, who will each submit 2 reports. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 1,500 hours (6,000 responses × 0.25 hours per response).

Our estimated burden for the information collection reflects an overall increase of 157 hours and a corresponding increase of 630 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: January 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02172 Filed 2–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2109]

Sami Anwar; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying a request for a hearing submitted by Sami Anwar (Anwar) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Anwar from providing services in any capacity to a person having an approved or pending drug product application. FDA bases this order on a finding that Anwar was convicted of felonies under Federal law for conduct relating to the development or approval of any drug product or otherwise relating to the regulation of a drug product under the FD&C Act. Anwar failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable February 2, 2023.

ADDRESSES: Any application for special termination of debarment by Anwar under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: Your application must include the Docket No. FDA–2020–N–2109. An application will be placed in the docket and, unless submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)) mandates permanent debarment if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the FD&C Act.

On October 1, 2020, the U.S. District Court for the Eastern District of Washington entered a judgment against Anwar, after a jury verdict, for 24 counts of wire fraud in violation of 18 U.S.C. 1349, 15 counts of mail fraud in violation of 18 U.S.C. 1341, 1 count of conspiracy to commit mail fraud in violation of 18 U.S.C. 371, 6 counts of fraudulently obtaining controlled substances in violation of 21 U.S.C. 843(a)(3), and 1 count of furnishing false or fraudulent material information to

the Drug Enforcement Administration in violation of 21 U.S.C. 843(a)(4)(A). As described below, the basis of Anwar's convictions stems from Anwar and his companies' falsifying research data for human clinical trials, including forging and falsifying documents to make it appear as though such clinical trials were performed and supervised by a qualified and licensed physician and falsifying medical records and data to admit dozens of ineligible subjects into the clinical trials.

By letter dated January 6, 2021, FDA's Office of Regulatory Affairs (ORA) notified Anwar of a proposal to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application and provided him an opportunity to request a hearing. As explained in the notice, the basis for the proposed debarment is Anwar's felony convictions in the U.S. District Court for the Eastern District of Washington. According to ORA, Anwar is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), that he was convicted of felonies under Federal law for conduct relating to the development or approval of any drug product or otherwise relating to the regulation of a drug product under the FD&C Act.

The proposal to debar states that the convictions relate to Anwar's role as owner and operator of Mid-Columbia Research LLC and Zain Research LLC, contract research organizations that oversaw and conducted clinical research trials on a contract basis for various drug sponsors. As described in the proposal, Anwar directed and carried out a conspiracy to have his companies fraudulently pose as legitimate human clinical research trial sites, and Anwar provided false clinical research trial data regarding drug safety and drug efficacy to dozens of drug companies and, through them, FDA, which regulates human clinical trials in the United States. Anwar also posed as a doctor and forged the signatures of the doctors he employed. In addition, Anwar directed his employees to assist in committing the fraud, including: (1) falsifying medical records and data to admit dozens of ineligible research subjects, (2) falsifying research data vital signs, (3) stealing blood samples taken from patients without their knowledge or consent, (4) directing patients to dispose of study medications and then falsely record dispensing as required by the study, (5) fraudulently obtaining and acquiring opioids intended to be dispensed to study subjects, and (6) falsifying subject diaries. In the proposal to debar, ORA found that Anwar's convictions, and underlying conduct, relate to the process for development or approval, including the process for development or approval, of any drug product and for conduct relating to the regulation of any drug product under the FD&C Act.

In a letter dated January 22, 2021, Anwar submitted a ''request for an extension of the hearing.'' This letter did not contain a request for a hearing, but the Director of the Office of Scientific Integrity, who has the authority to rule upon debarment matters, construed it as one. In addition, Anwar was given an extension to submit any information or factual analyses in support of his request for a hearing until April 15, 2021. Anwar has not filed any additional information to support his request.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Anwar's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

Since Anwar has not presented any information to support his hearing request, the Chief Scientist concludes that Anwar failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, the Chief Scientist denies Anwar's request for a hearing.

II. Findings and Order

The Chief Scientist, under section 306(a)(2) of the FD&C Act and under the authority delegated to her, finds that Sami Anwar has been convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing findings, Sami Anwar is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Anwar, in any capacity during his period of debarment, will be subject to civil money penalties. See section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Anwar, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. See section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Anwar during his period of debarment.

Dated: January 27, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023–02161 Filed 2–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on FDA's website entitled ''Postmarketing Requirements and Commitments: Reports'' (*https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/ucm064436.htm*).

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or Diane Maloney, Center for Biologics